DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 8 1996

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Andre Zagame,
President
MÉDICAL Z, S.A.
BP 39, 55, Rue De L'Église
61110 Rémalard, France

Dear Mr. Zagame:

During an inspection of your firm located in San Antonio, Texas on June 24, 1996, our Investigator determined that your firm imports and distributes scar management gel products. The Médigel Z™ line of products distributed under several names, including, Médipatch™, Mammopatch™, Abdopatch™, etc., are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501 (f) (1) (B) of the Act in that they are class III devices under section 513 (f) and do not have an approved application for premarket approval in effect pursuant to section 515 (a) or an approved application for an investigational device exemption under section 520 (g).

Additionally, the above-stated inspection revealed that these devices are misbranded within the meaning of section 502 (o) of the Act in that a notice or other information respecting the devices was not provided to the FDA as required by section 510 (k).

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Given the serious nature of these violations of the Act, all Médigel Z™ line of products manufactured by Médical Z, S.A., Rémalard, France, may be detained without physical examination upon entry into the United States until these violations are corrected.

In order to remove the devices from detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review, and submit a premarket notification [section 510(k)] for the current processes used at your facility for the manufacturing of Medical Z scar management gel products. After we notify you that the response is adequate, and your section 510(k) has been cleared, your products may resume entry into this country.

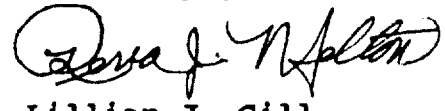
Please notify this office in writing within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. If the documentation is not in English, please provide a translation to facilitate our review.

Your response should be sent to:

Mr. George Kroehling, Chief
General Surgery Devices Branch, HFZ-323
Office of Compliance
Division of Enforcement I
Center for Devices and Radiological Health
U.S. Food and Drug Administration
2098 Gaither Road
Rockville, MD 20850 U.S.A.

Should you require any assistance in understanding the contents of this letter, do not hesitate to contact Mr. Joseph L. Salyer at the above address or at (301)-594-4595, Ext.175 or fax (301)-594-4636.

Sincerely yours,



for/ Lillian J. Gill,
Director
Office of Compliance
Center for Devices and
Radiological Health

CC: Mr. Tiff Worley,
Director, Advisor & Consultant
Medical Z Corporation
210 Rosedale Tower
1700 W. Hwy. 38
Roseville, MN 55113

Mr. Gregory L. Holdsworth,
General Manager
Medical Z Corporation
6800 Alamo Downs Parkway
San Antonio, TX 78238